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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,598	02/14/2000	BERNARD CHARLES SHERMAN	2051-36	6120

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[REDACTED] EXAMINER

PULLIAM, AMY E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/485,598	SHERMAN, BERNARD CHARLES
Examiner	Art Unit	
Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 27 November 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-20 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Receipt of Papers***

Receipt is acknowledged of the Request for Extension of Time, Request for Continued Examination, Preliminary Amendment D, and the Declaration, all received by the Office November 27, 2002.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,485,744. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentable distinct from the reference claim(s) because the

examiner claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to the claims of US Patent 6,485,744. That is, the claims of US Patent 6,485,744 fall entirely within the scope of the claims of the instant application, or, in other words, the claims of the US Patent are anticipated by the claims of the instant application. More specifically, the instant application requires a composition comprising cefuroxime axetil and an excipient, with later claims specifying that excipient as sorbitol. The prior US Patent requires a composition comprising the same drug and zinc chloride. The instant application is generic to the US Patent because the broad claims of the application require only drug and excipient. Additionally, the claims of the instant application contain comprising language, therefore permitting additional excipients to be included, such as the zinc chloride claimed in the prior Patent.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,865,851 to James *et al.* in view of US Patent 5,776,495 to Duclos *et al.*.

James *et al.* disclose cefuroxime axetil in particulate form, wherein the particles can be incorporated into pharmaceutical compositions for oral administration (abstract). More specifically, James *et al.* teach that the pharmaceutical compositions may be a dry product for direct administration to be washed down with water or an appropriate liquid. Additionally, the pharmaceutical composition may contain pharmaceutically acceptable additives, including sorbitol (c 5, 130-46). Lastly, James *et al.* teach that the particles of the invention may be granulated together with the additives using conventional techniques (c 5, 162-64). James *et al.* lack the teaching of a co-precipitate.

Duclos *et al.* disclose a process for the production of a solid dispersion of at least one therapeutic agent in a carrier, comprising dissolving at least one therapeutic agent in an organic solvent containing a very hydrophilic polymer and evaporating the solvent to dryness to form a co-precipitate. Duclos *et al.* also teach the products which result from the co-precipitate and their therapeutic methods of use (abstract). Duclos *et al.* also teach a wide range of active agents which can be used in the formulation, including cefuroxime as well as a variety of excipients, including polyvinylpyrrolidone (c 5, 110 and c 2, 130-32). Duclos *et al.* also teach that examples of the organic solvent include ethanol and acetone, among others (c 3, 110-20).

It is recognized that James *et al.* in view of Duclos *et al.* do not teach Applicant's claimed dissolution times. However, it is the position of the examiner that these times are a property of the formulation, which is rendered obvious by a suggestion of the formulation itself. In other words, because James in view of Duclos suggest the co-precipitate of cefuroxime axetil and an excipient, then they also suggest the dissolution profile of said composition.

One of ordinary skill in the art would have been motivated to combine the teachings of James *et al.* and Duclos *et al.*. James *et al.* teach a pharmaceutical composition comprising a mixture of cefuroxime axetil and common excipients, such as sorbitol. Duclos *et al.* teaches a general teaching to co-precipitates, and their benefits, which includes the active component being conveyed quickly and completely in solubilized form in order to allow quick absorption in the reduced space of the digestive tract. Additionally, Duclos *et al.* teach that the active agent can be one of many known actives, including the drug cefuroxime. It is the position of the examiner that one of ordinary skill in the art would have been motivated to combine the teachings of the above references, in order to make a drug/ excipient which is mixed at the molecular level, rather than the superficial level. Duclos *et al.* give the advantages for such a formulation. Furthermore, Duclos *et al.* specifically teach that cefuroxime is one of the actives which can benefit from the co-precipitate type of formulation. For all of the above reasons, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

#### *Additional Comments*

Regarding Applicant's previously submitted declaration, it is brought to Applicant's attention that the declaration discussed Applicant's claimed invention as containing sorbitol and cefuroxime axetil. This is not commensurate with the scope of the instant claims, as independent claim 1 requires only cefuroxime axetil and a generic excipient. It is advised that the claims be adapted to be commensurate in scope with the data provided in the declaration.

#### *Conclusion*

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam  
Patent Examiner  
AU 1615  
February 19, 2003

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